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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,816	03/31/2000	Gavin Paul Vinson	BKY 2 040 -1- 1- 1	3602

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Jay F Moldovanyi
Fay Sharpe Fagan Minnich & McKee LLP
1100 Superior Avenue 7th Floor
Cleveland, OH 44114-2518

EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 11/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/540,816	VINSON ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11 and 14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14-17 and 19* is/are rejected.

7)☒ Claim(s) *3 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I in Paper No. 7 is acknowledged. The amendment filed 8-6-02 (paper no. 8) is acknowledged and entered into the record.

2. Claims 8-10 and 12-13 are canceled without prejudice. Claims 14-19 are newly added. Therefore claims 1-7, 11, and 14-19 are pending and examined on the merits.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 27 September 1993. It is noted, however, that applicant has not filed a certified copy of the 9319877.8 application as required by 35 U.S.C. 119(b).

4. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 08/624,374 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be made in this application. In making such claim, applicant may simply identify the application containing the priority papers.

Specification

5. The disclosure is objected to because of the following informalities: priority data needs to be updated to reflect the current status of the parent application (08/624, 374).

Appropriate correction is required.

Claim Objections

6. Claims 3 and 7 are objected to because of the following informalities: claims 3 and 7 recite specific sequences which require an associated sequence identification number. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

7. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the active steps. One of skill in the art does not know how to perform the diagnostic test, for what purpose the diagnostic test is being performed, and what disease is being diagnosed.

8. Claims 1-3, 5-6, 11, and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claims 1, and dependent claims thereof, in the recitation of the term "hybridoma", it is unclear as to which hybridoma is being referred. As such the metes and bounds of the term cannot be determined.

10. Regarding claims 5 and dependent claims thereof, in the recitation of the term "monoclonal antibody", it is unclear as to which monoclonal antibody is being referred. As such, the metes and bounds of the term cannot be determined.

11. Regarding claims 2, 6, and 14-15 in the recitation of "amino acid residues 8-17", it is unclear as to what amino acids are being referred. The metes and bounds of the

term cannot be determined because amino acid 8-17 of the instant invention may be amino acids 9-18 of another invention, depending on what the applicant or another skilled in the art determines as position 1 of the AT1 subtype of the angiotensin II receptor.

Claim Rejections - 35 USC § 112, 1st paragraph

12. Claims 4 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the recited cell lines are required to practice the claimed invention, because they are specifically required in the claims. As required elements they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the cell lines listed in claim 7. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the cell lines of claim 4 or 19, and they do not appear to be readily available material. Deposit of the cell lines would satisfy the enablement requirements of 35 U.S.C. 112. While the specification states on page 3 that the cell lines have been deposited "under the Budapest treaty", the specification does not indicate the terms of the deposit.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 112, 1st paragraph

13. Claims 1-3, 5-6, 11, and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hybridoma of European Collection of Animal Cell Cultures Accession No. 930720117 and a monoclonal antibody that binds to amino acid 8-17 of SEQ ID No: 1 of the AT1 subtype of the angiotensin II receptor, does not reasonably provide enablement for all hybridomas or monoclonal antibodies that bind to AT1 subtype of the angiotensin II receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond

that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The nature of the invention: The claims of the instant invention are drawn to hybridomas and monoclonal antibodies that are capable of binding to the AT1 subtype of the angiotensin II receptor and a diagnostic kit comprising such an antibody.

The amount of direction or guidance present and the presence or absence of working examples: The working examples of the instant invention are drawn to a hydridoma cell line of European Collection of Animal Cell Cultures Accession No. 930720117, which produces a monoclonal antibody that is specific to amino acids 8-17 of SEQ ID No: 1. The specification teaches the generation, charaterization, and functional analysis of the antibody produced by hydridoma cell line of accession no. 930720117. However, nowhere in the specification does it disclose or teach the generation or the characterization of any other antibody produced by any other hydridoma cell line. On

page 9 under the "Results" section, the specification describes "other hydridoma clones", but does not describe the antibodies generated from those "other hydridoma clones" nor do they specifically describe the hydridoma cell lines produced.

The breadth of the claims and the quantity of experimentation needed: Given the broad range of hybridomas and monoclonal antibodies to AT1 subtype of angiotensin II receptor encompassed within the claims, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 1-7,11, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Barker *et al* (J. Mol. Endocrinol 1993 Oct; 11(2):241-5). Claims 1-7 are drawn to a hybridoma cell line that produces an antibody that is specific for amino acids 8-17 of AT1 subtype of angiotensin II receptor. Barker *et al* teach an antibody that specifically binds to amino acids 8-17 of AT1 subtype of angiotensin II receptor produced by the same hybridoma cell line. Since claims 11 and 18 are an intended use of the product, it too, is anticipated by the Barker *et al* reference. This rejection may be obviated upon submission of the foreign priority papers.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,063,620. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention are drawn to a hydridoma cell line which produces a monoclonal antibody that is capable of binding to the AT1 subtype of angiotensin II receptor and a monoclonal antibody that binds to the AT1 subtype of angiotensin II receptor, wherein the peptide used to generate the hybridoma and monoclonal antibody disclosed as amino acid 8-17 of AT1 subtype of angiotensin II receptor (SEQ ID No: 1). The instant invention is obvious over the prior US Patent No. 6,063,620 because the prior US Patent claims a hydridoma cell line that produces a monoclonal antibody that is capable of binding to the AT1 subtype of angiotensin II receptor and a monoclonal antibody that binds to the AT1 subtype of angiotensin II receptor. Furthermore, the claims of the prior US Patent encompasses a monoclonal

antibody that is specific for amino acids 8-17 of AT1 subtype of angiotensin II receptor (disclosed as SEQ ID No: 1).

Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
October 31, 2002

ALI R. SALIMI
PRIMARY EXAMINER